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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/825,144

04/03/2001

Matthias Krause

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EXAMINER

HADDAD, MAHER M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 02/12/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,144

Applicant(s)

KRAUSE ET AL.

Examiner

Maher M. Haddad

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,9,26,30,34,39,42,46 and 73-84 is/are pending in the application.
- 4a) Of the above claim(s) 6,9,34,46 and 84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,26,30,39,42 and 73-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 12/02/02 (Paper No. 13), is acknowledged.

Claims 1, 2, 4, 6, 9, 26, 30, 34, 39, 42, 46 and 73-84 are pending.

Claims 6, 9, 34, 46 and 84 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 1, 2, 4, 26, 30, 39, 42 and 73-83 are under examination as they read on a method for inhibiting cytoskeletal rearrangement, a method for inhibiting a T cell response, and a method for increasing platelet aggregation with an EVH1 binding peptide *are under consideration in the instant application*.

2. The following new ground of rejection is necessitated by the amendment filed on 12/02/02, paper No. 13.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-2, 4 and 73-77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The phrase "that comprises Fyb/SLAP and Ena/VASP proteins that form a complex" claimed in claim 1, lines 1-2, represent a departure from the specification and the claims as originally filed.

Applicant's amendment filed 12-02-02 does not point to the specification for support for the newly added limitations "that comprises Fyb/SLAP and Ena/VASP proteins that form a complex" as claimed in claim 1. However, the specification does not provide a clear support of "that comprises Fyb/SLAP and Ena/VASP proteins that form a complex". The instant claims now recite a limitation, which was not clearly disclosed in the specification and claims as originally filed.

5. In view of the amendment filed on 12/02/02 (Paper No. 13), only the following rejections are remained.

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6. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-2, 4 and 73-76 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A. Claim 1 is indefinite in the recitation of “cell fragment” because it is unclear whether the “cell fragment” refers to the nucleus, cell membrane, Golgi apparatus, cytoskeletal elements, nuclear membrane, or any other particular cell fragment.

Applicant’s arguments, filed 12/02/02 (Paper No. 13), have been fully considered, but have not been found convincing.

Applicant asserts that the term “fragment” is commonly understood to be “a part broken off or detached”. Applicant further argues that “cell fragment” would be understood by one of ordinary skill in the art to be a part of a cell that comprises Fyb/SLAP and Ena/VASP proteins that form a complex.

Contrary to Applicant’s assertions, the use of term “cell fragment” in the instant application refers to the number of cell fragments, which renders the claims indefinite. Further, it is unclear how a skill in the art would inhibit cytoskeletal rearrangement in a detached cell fragment, while the detached cell fragment is no longer maintain the cytoskeletal integrity.

8. Claims 1-2, 4, 26, 30, 39, 42 and 73-83 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inhibiting cytoskeletal rearrangement in a T cell or a platelet, a method for inhibiting a T cell response and a method for increasing platelet aggregation comprising contacting the T cell or platelet with an amount of a Fyb/SLAP complex inhibitor sufficient to inhibit the formation of a complex of an Ena/VASP protein and a Fyb/SLAP protein wherein the Fyb/SLAP inhibitor is EVH1 binding peptide FPPPP (SEQ ID NO:15), does not reasonably provide enablement for a method for inhibiting cytoskeletal rearrangement in “any cell or cell fragment” that comprises Fyb/SLAP and Ena/VASP proteins that form a complex in claim 1, a method for inhibiting a T cell response to T cell receptor stimulation and a method for increasing platelet aggregation comprising contacting the “cell or cell fragment” with an amount of “any Fyb/SLAP complex inhibitor” sufficient to inhibit the formation of a complex of an Ena/VASP protein and a Fyb/SLAP protein wherein the Fyb/SLAP complex inhibitor binds to the EVH1 domain of the Ena/VASP protein and inhibits binding of the Ena/VASP protein to Fyb/SLAP protein in claims 2, 26, 30, 39 and 42; or the Fyb/SLAP complex inhibitor “comprises” the peptide FPPP (SEQ ID NO:15) or any “peptide mimetic having an equivalent binding specificity” in claims 4, 79 and 82. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

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make and/or use the invention commensurate in scope with these claims essentially for the same reasons set forth in the previous Office Action, paper No. 11, mailed 7/30/02.

Applicant's arguments, filed 12/02/02 (Paper No. 13), have been fully considered, but have not been found convincing.

Applicant argues that the claim amendment to claim 1 to clarify that the cell or cell fragment is a cell or cell fragment comprising Fyb/SLAP and Ena/VASP proteins that form a complex obviates the basis of the rejection.

However, as noted in the previous Office action that it is unclear whether or not the claimed method would function in "any cell" or "any cell fragment". Since Fyb/SLAP is an adapter protein expressed in T cells and myeloid cells (see Griffiths et al., 293:2260-2263, 2001) (of records), the cytoskeletal rearrangement effect of the Fyb/SLAP complex inhibitor on cells other than T cells and myeloid cells is unpredictable. Further, there is insufficient guidance in the specification on how to inhibit cytoskeletal rearrangement in any cell or any cell fragment other than T cell. It is noted that the amendment to claim 1 has added the function limitation to the cell or cell fragment. However, the amendment does not obviate the issues of enablement rejection set forth in the previous office action of 7/30/02. Applicant is relying upon certain biological activities and the disclosure of a single species to support an entire genus.

Applicant argues that Applicants are not claiming specific inhibitor agents, but rather are claiming methods of using such agents. Applicant further argues that methods of testing the ability of putative inhibitors to inhibit Fyb/SLAP binding to Ena/VASP are described in the Example 3 of the specification.

Contrary to Applicant's assertions, in order to satisfy the U.S.C 112, 1st paragraph, the specification has to teach how to make and/or use the invention, not how to test to identify the invention. Until the time when Fyb/SLAP complex inhibitors are found, then one skill in the art can make them. Further, the specification fails to provide sufficient guidance as to which Fyb/SLAP complex inhibitor other than SEQ ID NO: 15 is essential for inhibiting cytoskeletal rearrangement, T cell response or increasing platelet aggregation and which changes can be made in the structure of SEQ ID NO: 15 and still maintained the same function. The claims as written encompass a broad genus of polypeptides with an unlimited number of possibilities with regard to the length of the polypeptide sequence. Further, the enablement issues of making the protein still remain because the specification does not teach and provide sufficient guidance as to which amino acid of SEQ ID NO:15 would have been altered such that the resultant polypeptide would have retained the function of inhibiting the interaction between Fyb/SLAP and Ena/VASP by binding to EVH1.

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Applicant argues that all of the Wands factors should be considered for a proper analysis and a finding of nonenablement must be based on the evidence as a whole, and further in view of the state of the art at the time of filing, leads one to the reasonable conclusion that practicing the invention would not require undue experimentation. Applicant argues that one ordinary skill in the art would be able to use to determine the inhibitory characteristics and effects of putative inhibitor agents on the binding of Fyb/SLAP and Ena/VASP proteins.

However, one skilled in the art at the time of the invention was made would not be able to predict which compounds such as SEQ ID NO: 15 will inhibit cytoskeletal rearrangement and inhibit T cell response or increase platelet aggregation. Consequently the skilled artisan would not know how to use the instant invention as broadly claimed. While experimental testing techniques using screening assays to detect the binding compounds are available, it is not routine in the art to use such methods when the expectation of success is unpredictable based on the instant disclosure. Thus, it would require an undue amount of experimentation of one skilled in the art to practice the invention as broadly claimed.

Applicant argues in conjunction with In re Howarth that the level of skill in the art has an important effect on the amount of guidance which must be provided to enable the invention.

However, applicant is relying on a method of screening to identify putative compounds that can be used in the claimed methods, the specification does not disclose how to make the putative Fyb/SLAP complex inhibitors.

9. Claims 1-2, 4, 26, 30, 39, 42 and 73-83 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons set forth in the previous Office Action, paper No. 11, mailed 7/30/02.

Applicant's arguments, filed 12/02/02 (Paper No. 13), have been fully considered, but have not been found convincing.

Applicant argues that an adequate written description can be achieved by clear description of the claimed invention to allow one of ordinary skill in the art to recognize that the inventors invented the claimed invention. Applicant argues that the claimed invention is not agents that can be used to inhibit cytoskeletal rearrangement by rather methods of inhibiting cytoskeletal rearrangement in a cell or cell fragment that comprises Fyb/SLAP and Ena/VASP protein that form a complex.

However, the Examiner notes that the claimed invention which is drawn to a genus may be adequately described if there is a (1) sufficient description of a representative number of species, or (2) by disclosure of relevant, identifying characteristics sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. To satisfy the disclosure of a "representative number of species" will depend on whether one of skill in the art would

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recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. "Relevant, identifying characteristics" include structure or other physical and /or chemical properties, functional characteristics coupled with a known or disclosed correlation between function and structure, or a combination of such identifying characteristics sufficient to show the applicant was in possession of the claimed genus. (see Revised Guidelines for the Examination of Patent Applications Under the 35 U.S.C.112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No.4, pages 1099-1111, Friday January 5, 2001).

In the instant case, however, there is no described or art-recognized correlation or relationship between the structure of the invention, the Fyb/SLAP complex inhibitor and it's inhibition of cytoskeletal rearrangement and T cell response or increase in platelet aggregation function, the feature deemed essential to the instant invention. Therefore, one of skill in the art would not envisage, based on the instant disclosure, the claimed genus of cells or cell fragments or Fyb/SLAP complex inhibitor, wherein the Fyb/SLAP complex inhibitor comprising a peptide mimetic having an equivalent binding specificity which retain the features essential to the instant invention.

10. No claim allowed

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad, whose telephone number is (703) 306-3472. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
February 10, 2003


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